IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Takashi KADOWAKI et al.

Serial No.:

10/591,490

Group No.:

Filed:

09/01/2006

Examiner:

For:

Agents For Regulating Adiponectin Receptor Expression

INFORMATION DISCLOSURE STATEMENT

MS PCT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 8, 2007.

(, ()

Dear Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. § 1.56 and § 1.97. The Examiner is requested to make these citations of official record in this application:

- Publication No. US 2004/0241802 A1 of Kadowaki *et al.*, "Adiponectin receptor and gene encoding same," (2004) as English translation of related PCT application;
- Publication No. WO 2004/061108 A1 of Kadowaki et al., "Adiponectin receptor and gene encoding same," (2004) in Japanese accompanied by English translation of related national entry application;
- Berg et al., "The adipocyte-secreted protein Acrp30 enhances hepatic insulin action,"
 Nature Medicine, 7:947-953 (2001);
- Biggs III et al., "Protein kinase B/Akt-mediated phosphorylation promotes nuclear exclusion of the winged helix transcription factor FKHR1," Proc Natl Acad Sci USA, 96:7421-7426 (1999);

- Brunet *et al.*, "Akt promotes cell survival by phosphorylating and inhibiting a forkhead transcription factor," *Cell*, 96:857-868 (1999);
- Friedman et al., "Phosphoenolpyruvate carboxykinase (GTP) gene transcription and hyperglycemia are regulated by glucocorticoids in genetically obese db/db transgenic mice," J Biol Chem, 272:31475-31481 (1997);
- Fruebis et al., "Proteolytic cleavage product of 30-kDa adipocyte complement-related protein increases fatty acid oxidation in muscle and causes weight loss in mice," Proc Natl Acad Sci USA, 98:2005-2010 (2001);
- Guo *et al.*, "Phosphorylation of serine 256 by protein kinase B disrupts transactivation by FKHR and mediates effects of insulin on insulin-like growth factor-binding protein-1 promoter activity through a conserved insulin response sequence," *J Biol Chem*, 274:17184-17192 (1999);
- Herzig *et al.*, "CREB regulates hepatic gluconeogenesis through the coactivator PGC-1," *Nature*, 413:179-183 (2001);
- Hu et al., "AdipoQ is a novel adipose-specific gene dysregulated in obesity," *J Biol Chem*, 271:10697-10703 (1996);
- Kadowaki, "Insights into insulin resistance and type 2 diabetes from knockout mouse models," *J Clin Invest*, 106:459-465 (2000);
- Kubota et al., "Disruption of adiponectin causes insulin resistance and neointimal formation," *J Biol Chem*, 277:25863-25866 (2002);
- Levine et al., "Toxicologic evaluation of streptozotocin (NSC 85998) in mice, dogs and monkeys," *Drug Chem Toxicol*, 3:201-212 (1980);
- Maeda et al., "cDNA cloning and expression of a novel adipose specific collagen-like factor, apM1 (Adipose Most Abundant Gene Transcript 1), Biochem Biophys Res Commun, 221:286-289 (1996);
- Maeda et al., "Diet-induced insulin resistance in mice lacking adiponectin/ACRP30,"
 Nature Medicine, 8:731-737 (2002);
- Nakae et al., "Insulin stimulates phosphorylation of the forkhead transcription factor
 FKHR on serine 253 through a wortmannin-sensitive pathway," J Biol Chem, 274:1598215985 (1999);

- Nakae *et al.*, "The forkhead transcription factor Foxo1 (Fkhr) confers insulin sensitivity onto glucose-6-phosphatase expression," *J Clin Invest*, 108:1359-1367 (2001);
- Nakano et al., "Isolation and characterization of GBP28, a novel gelatin-binding protein purified from human plasma," J Biochem, 120:803-812 (1996);
- Ouchi et al., "Adipocyte-derived plasma protein, adiponectin, suppresses lipid accumulation and class A scavenger receptor expression in human monocyte-derived macrophages," Circulation, 103:1057-1063 (2001);
- Rakieten *et al.*, "Studies on the diabetogenic action of streptozotocin (NSC-37917)," *Cancer Chemother Rep*, 29:91-98 (1963);
- Scheer *et al.*, "Constitutively active mutants of the α1B-adrenergic receptor: role of highly conserved polar amino acids in receptor action," *EMBO J*, 15:3566-3578 (1996);
- Scherer et al., "A novel serum protein similar to C1q, produced exclusively in adipocytes," J Biol Chem, 270:26746-26749 (1995);
- Seglen, "Preparation of isolated rat liver cells," *Methods Cell Biol*, 13:29-83 (1976);
- Shepherd *et al.*, "Phosphoinositide 3-kinase: the key switch mechanism in insulin signaling," *Biochem J*, 333:471-490 (1998);
- Takaishi *et al.*, "Regulation of nuclear translocation of Forkhead transcription factor AFX by protein kinase B," *Proc Natl Acad Sci USA*, 96:11836-11841 (1999);
- Tomas *et al.*, "Enhanced muscle fat oxidation and glucose transport by ACRP30 globular domain: Acetyl-CoA carboxylase inhibition and AMP-activated protein kinase activation," *Proc Natl Acad Sci USA*, 99:16309-16313 (2002);
- Tsuchida *et al.*, "Insulin/Foxo1 pathway regulates expression levels of adiponectin receptors and adiponectin sensitivity," *J Biol Chem*, 279:30817-30822 (2004);
- Virkamaki *et al.*, "Protein-protein interaction in insulin signaling and the molecular mechanisms of insulin resistance," *J Clin Invest*, 108:1001-1013 (2001);
- Wess, "G-protein-coupled receptors: Molecular mechanisms involved in receptor activation and selectivity of G-protein recognition," FASEB J, 11:346-354 (1997);
- Yamauchi et al., "The fat-derived hormone adiponectin reverses insulin resistance associated with both lipoatrophy and obesity," *Nature Medicine*, 7:941-946 (2001);

- Yamauchi et al., "Inhibition of RXR and PPARγ ameliorates diet-induced obesity and type 2 diabetes," J Clin Invest, 108:1001-1013 (2001);
- Yamauchi et al., "Adiponectin stimulates glucose utilization and fatty-acid oxidation by activating AMP-activated protein kinase," *Nature Medicine*, 8:1288-1295 (2002);
- Yamauchi et al., "Globular adiponectin protected ob/ob mice from diabetes and ApoE-deficient mice from atherosclerosis," J Biol Chem, 278:2461-2468 (2003);
- Yamauchi et al., "Cloning of adiponectin receptors that mediate antidiabetic metabolic effects," *Nature*, 324:762-769 (2003); and
- Yokomizo *et al.*, "A G-protein-coupled receptor for leukotriene B₄ that mediates chemotaxis," *Nature*, 387:620-624 (1997).

This Information Disclosure Statement under 37 C.F.R. § 1.56 and § 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: May 8, 2007

Christine A. Lekutis Registration No. 51,934

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105 415/904-6500 FORM PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office

Attorney Docket No.:	SHIMIZU-13116	Serial N

Applicant: Takashi Kadowaki

lo.: 10/591,490

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)

(Use Several Sheets If		Filing or 371(c) Date: 09/01			09/01/2006	01/2006 Group Art Unit:				
				U.S. PATENT DOC	UMENTS					
Examiner Initials	Cite No.	Document / Publication / Applicant / Fatent Number Issue Date Applicant / F		ant / Patentee	Class	Subclass	Filing	g Date		
	1	2004/0241802		Kado	owaki et al.				-	
·										
		F (OREIGN PATENTS C	R PUBLISHED FOR	REIGN PATENT APPL	ICATIONS		1		
•		Document Number	Publication Date	Country	/ Patent Office	Class	Subclass	Trans Yes	slation N	
	2	WO 2004/061108		PCT						
		OTHER	DOCUMENTS (Inclu	ding Author, Title, D	ate, Relevant Pages, Pla	ce of Publication)				
	3	Berg et al., "The adi	pocyte-secreted proteir	Acrp30 enhances he	patic insulin action," No	ture Medicine, 7:9	47-953 (2001)	·		
	4		tein kinase B/Akt-med USA, 96:7421-7426 (19		promotes nuclear exclu	sion of the winged	helix transcription	n factor FK	HR1,"	
	5	Brunet et al., "Akt promotes cell survival by phosphorylating and inhibiting a forkhead transcription factor," Cell, 96:857-868 (1999)								
	6	Friedman et al., "Phosphoenolpyruvate carboxykinase (GTP) gene transcription and hyperglycemia are regulated by glucocorticoids in genetically obese db/db transgenic mice," J Biol Chem, 272:31475-31481 (1997)								
	7	Fruebis et al., "Proteolytic cleavage product of 30-kDa adipocyte complement-related protein increases fatty acid oxidation in muscle and cause weight loss in mice," Proc Natl Acad Sci USA, 98:2005-2010 (2001)								
	8	Guo et al., "Phosphorylation of serine 256 by protein kinase B disrupts transactivation by FKHR and mediates effects of insulin on insulin-like growth factor-binding protein-1 promoter activity through a conserved insulin response sequence," J Biol Chem, 274:17184-17192 (1999)								
	9	Herzig et al., "CREB regulates hepatic gluconeogenesis through the coactivator PGC-1," Nature, 413:179-183 (2001)								
	10	Hu et al., "AdipoQ is a novel adipose-specific gene dysregulated in obesity," J Biol Chem, 271:10697-10703 (1996)								
	11	Kadowaki, "Insights into insulin resistance and type 2 diabetes from knockout mouse models," J Clin Invest, 106:459-465 (2000)								
	12	Kubota et al., "Disruption of adiponectin causes insulin resistance and neointimal formation," J Biol Chem, 277:25863-25866 (2002)								
	13	Levine et al., "Toxic	ologic evaluation of st	reptozotocin (NSC 8:	5998) in mice, dogs and	monkeys," Drug C	hem Toxicol, 3:20	1-212 (198	0)	
	14	Maeda et al., "cDNA cloning and expression of a novel adipose specific collagen-like factor, apM1 (Adipose Most Abundant Gene Transcrip Biochem Biophys Res Commun, 221:286-289 (1996)								
	15	Maeda et al., "Diet-i	nduced insulin resistan	ce in mice lacking ad	liponectin/ACRP30," Na	ture Medicine, 8:7	31-737 (2002)			
-	16	Nakae et al., "Insulin stimulates phosphorylation of the forkhead transcription factor FKHR on serine 253 through a wortmannin-sensitive pathway," J Biol Chem, 274:15982-15985 (1999)								
	17	Nakae et al., "The fo 108:1359-1367 (200		ector Foxol (Fkhr) co	nfers insulin sensitivity	onto glucose-6-pho	sphatase expressi	on," <i>J Clin</i>	Invest,	
	18	Nakano <i>et al.</i> , "Isola (1996)	tion and characterization	on of GBP28, a novel	gelatin-binding protein	purified from huma	an plasma," J Bio	chem, 120:8	303-81	
	19	Ouchi et al., "Adipocyte-derived plasma protein, adiponectin, suppresses lipid accumulation and class A scavenger receptor expression in hum monocyte-derived macrophages," Circulation, 103:1057-1063 (2001)								
	20	Rakieten et al., "Stu-	dies on the diabetogeni	c action of streptozot	ocin (NSC-37917)," Cal	ncer Chemother Re	p, 29:91-98 (1963)		
	21	Scheer et al., "Constitutively active mutants of the α1B-adrenergic receptor: role of highly conserved polar amino acids in receptor action," EMBO J, 15:3566-3578 (1996)								
	22	Scherer et al., "A no	vel serum protein simi	lar to C1q, produced	exclusively in adipocyte	s," J Biol Chem, 27	0:26746-26749 (1995)		
	23	Seglen, "Preparation	of isolated rat liver ce	lls," Methods Cell Bio	ol, 13:29-83 (1976)					
	24	Shepherd et al., "Pho	osphoinositide 3-kinase	: the key switch med	hanism in insulin signali	ng," <i>Biochem J</i> , 33	3:471-490 (1998)	· · · · · · · · · · · · · · · · · · ·	***	
	25	Takaishi et al., "Regulation of nuclear translocation of Forkhead transcription factor AFX by protein kinase B," Proc Natl Acad Sci USA, 96:11836-11841 (1999)								
		-			Date Considered:					
xaminer:										





FORM PTO-1449 U.S. Department of Commerce (Modified) Patent and Trademark Office

Attorney Docket No.: SHIMIZU-13116 Serial No.: 10/591,490

Applicant: Takashi Kadowaki

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) Filing or 371(c) Date: 09/01/2006 Group Art Unit: (37 CFR § 1.98(b)) OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication) Tomas et al., "Enhanced muscle fat oxidation and glucose transport by ACRP30 globular domain: Acetyl-CoA carboxylase inhibition and AMP-26 activated protein kinase activation," Proc Natl Acad Sci USA, 99:16309-16313 (2002) Tsuchida et al., "Insulin/Foxo 1 pathway regulates expression levels of adiponectin receptors and adiponectin sensitivity," J Biol Chem, 27 279:30817-30822 (2004) Virkamaki et al., "Protein-protein interaction in insulin signaling and the molecular mechanisms of insulin resistance," J Clin Invest, 108:1001-28 1013 (2001) Wess, "G-protein-coupled receptors: Molecular mechanisms involved in receptor activation and selectivity of G-protein recognition," FASEB J, 29 11:346-354 (1997) Yamauchi et al., "The fat-derived hormone adiponectin reverses insulin resistance associated with both lipoatrophy and obesity," Nature 30 Medicine, 7:941-946 (2001) Yamauchi et al., "Inhibition of RXR and PPARy ameliorates diet-induced obesity and type 2 diabetes," J Clin Invest, 108:1001-1013 (2001) 31 Yamauchi et al., "Adiponectin stimulates glucose utilization and fatty-acid oxidation by activating AMP-activated protein kinase," Nature 32 Medicine, 8:1288-1295 (2002) Yamauchi et al., "Globular adiponectin protected ob/ob mice from diabetes and ApoE-deficient mice from atherosclerosis," J Biol Chem, 33 278:2461-2468 (2003) 34 Yamauchi et al., "Cloning of adiponectin receptors that mediate antidiabetic metabolic effects," Nature, 324:762-769 (2003) Yokomizo et al., "A G-protein-coupled receptor for leukotriene B4 that mediates chemotaxis," Nature, 387:620-624 (1997) 35 Date Considered: EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next

communication to applicant.